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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,832	06/21/2001	Toshikazu Hirota	789 070	6274

25191 7590 07/28/2003

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,832

Applicant(s)

HIROTA ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 15-18, 22-25 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 15-18 22-25 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1634

FINAL ACTION

1. This action is in response to papers filed 19 May 2003 in which claims 1, 3 and 30 were amended. All of the amendments have been thoroughly reviewed and entered. The previous objections and rejections in the Office Action dated 18 December 2002 under 35 U.S.C. 112, first paragraph; under 35 U.S.C. 102(e); and under 35 U.S.C. 103(a) are maintained. The previous rejections under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments.

All of the arguments have been thoroughly reviewed and are discussed below.

Claims 1-4, 15-18, 22-25 and 30 are under prosecution.

Specification

2. The amendment filed 22 February 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Claim 30 was amended to recite "said base plate is non-permeable with respect to said capture solution". The specification fails to define or provide any disclosure to support such claim recitation. The specification teaches the base plate is glass (page 20, line 24-page 21, line 1). However, the specification fails to define or describe the broadly claimed "non-permeable" base plate. Therefore, the recitation introduces new matter into the disclosure of the invention.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

Applicant argues that the specification enables the recitation "non-permeable" base plate because the specification teaches a glass plate. The argument has been considered but is not found persuasive because while it is acknowledged that a glass plate is non-permeable with respect to a capture solution as claimed, the disclosed glass plate is but one example of an enormous genus of non-permeable base plate. The claims encompass the enormous genus of non-permeable base plates, but the specification merely teaches one species of the genus i.e. glass. Therefore, the amendment introduces an enormous genus into the specification which is not supported by the originally filed specification. As such, the amendment is objected to for introducing new matter into the specification.

Claim Rejections - 35 USC § 112

35 U.S.C. 112: first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "said base plate is non-permeable with respect to said capture solution" is added to the newly added claim 30. The specification fails to define or provide any disclosure to support such claim recitation. The specification teaches the base plate is glass

Art Unit: 1634.

(page 20, line 24-page 21, line 1). However, the specification fails to define or describe the broadly claimed "non-permeable" base plate.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

Response to Arguments

6. Applicant relies on the argument discussed above to overcome the rejection under 35 U.S.C. 112, first paragraph. The argument has been considered but is not found persuasive for the reasons stated above.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1634

8. Claims 3, 4, 17, 18, 24, 25 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Audeh et al (U.S. Patent Application Publication No. 2002/0015958 A1, filed 4 May 2000).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Regarding Claim 3, Audeh et al disclose a biochip comprising a large number of spots of capture solutions containing a capture material therein arranged on a base plate wherein said plurality of capture solutions each of which is adapted to specifically react with a specimen (i.e. hybridize) and provide information about a structure within the specimen (§ 37) and wherein said plurality of said spots are formed in which the concentration of the capture material varies from spot to spot and wherein each of said spots has a uniform detection sensitivity (§ 30 and 31 and Claim 33). Audeh et al do not teach the spots are supplied onto the base plate by means of an ink jet system. However, the courts have stated patentability is based on the product, not the process by which it is made. Therefore, the claimed biochip is unpatentable in view of the teaching of Audeh et al.

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Regarding Claim 4, Audeh et al disclose the biochip wherein the spots are formed from the same capture solution i.e. formed from the same colloidal suspension in water (§ 34). While the spots comprise different oligonucleotides and therefore do not consist of the same capture solutions, they are formed from the same solution as claimed.

Art Unit: 1634

Regarding Claims 17 and 18, Audeh et al disclose the biochip of Claims 3 and 4. While they do not teach the biochip spots are formed using an ink-jet system in which a sample solution is impacted onto said base plate after being discharged into the atmosphere and wherein a force of the discharge is controlled electronically, the courts have stated patentability is based on the product, not the process by which it is made. Additionally, the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). Because Audeh et al disclose the claimed structural components of the biochip, they disclose the biochip as claimed.

Regarding Claims 24 and 25, Audeh et al disclose the biochip of Claims 3 and 4. While they do not teach the biochip spots are formed using an ink-jet system in which a sample solution is impacted onto said base plate after being discharged into the atmosphere and wherein the number of times of discharge at each spot is controlled electronically, the courts have stated patentability is based on the product, not the process by which it is made. Additionally, the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). Because Audeh et al disclose the claimed structural components of the biochip, they disclose the biochip as claimed.

Regarding Claim 30, Audeh et al disclose the biochip of Claim 3 wherein the base plate is non-permeable with respect to said capture solution e.g. glass (§ 36).

Response to Arguments

9. Applicant argues that their method of using an ink jet process for supplying the capture solution spots onto the base plate yields spots that have more accurately and precisely controlled concentration per spot. Applicant further argues that because of this accurate and precise spotting, the claimed product (i.e. biochip) is not the same as that of the prior art wherein the spots are supplied using a pin. Applicant also discusses a negative aspects of

Art Unit: 1634

pin spotting i.e. when pins contact a previously spotted sample, some of the previously spotted sample is picked up by the pin and becomes a contaminant during subsequent spotting and because of this phenonmn cannot as accurately and precisely control spot concentration as required by the instant claims. For these reasons, Applicant argues that Audeh does not disclose the instant invention.

The arguments have been considered but are not found persuasive because Applicant has not provided factual evidence to support the assertions regarding dissimilarities between pin spotting and ink-jet spotting. Furthermore, any evidence supporting the assertion would be considered as prior art against the claims.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c).

When applicant states that something is prior art, it is taken as being available as prior art against the claims. Admitted prior art can be used in obviousness rejections. In re Nomiya, 509 F.2d 566, 184 USPQ 607, *611< (CCPA 1975) (Figures in the application labeled "prior art" held to be an admission that what was pictured was prior art relative to applicant's invention.) (see MPEP § 2128.02).

10. Claims 3, 4, 17, 18, 24, 25 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Mirzabekov et al (U.S. Patent No. 6,458,584 B1, filed 3 March 1999).

Art Unit: 1634

Regarding Claim 3, Mirzabekov et al disclose a biochip comprising a large number of spots of capture solutions containing a capture material therein arranged on a base plate wherein said plurality of capture solutions each of which is adapted to specifically react with a specimen (i.e. hybridize) and provide information about a structure within the specimen (Column 9, lines 20-30) and wherein said plurality of said spots are formed in which the concentration of the capture material varies from spot to spot and wherein each of said spots has a uniform detection sensitivity Column 18, lines 49-67) wherein the spots are supplied onto the base plate by means of an ink jet system i.e. peltier thermostated pin (Column 11, lines 45-48).

Regarding Claim 4, Mirzabekov et al disclose the biochip wherein the spots are formed from the same capture solution i.e. formed from the same oligonucleotide synthesis solution (Column 11, lines 15-31 and Column 12, lines 8-10). While the spots comprise different oligonucleotides and therefore do not consist of the same capture solutions, they are formed from the same solution as claimed.

Regarding Claims 17 and 18, Mirzabekov et al disclose the biochip of Claims 3 and 4 wherein the biochip spots are supplied using an ink-jet system i.e. peltier thermostated pin (Column 11, lines 45-48). They do not teach the supplying wherein a sample solution is impacted onto said base plate after being discharged into the atmosphere and wherein a force of the discharge is controlled electronically. However, the courts have stated patentability is based on the product, not the process by which it is made. Additionally, the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). Because Mirzabekov et al disclose the claimed structural components of the biochip, they disclose the biochip as claimed.

Regarding Claims 24 and 25, Mirzabekov et al disclose the biochip of Claims 3 and 4 wherein the biochip spots are supplied using an ink-jet system i.e. peltier thermostated pin

Art Unit: 1634

(Column 11, lines 45-48). They do not teach the supplying wherein a sample solution is impacted onto said base plate after being discharged into the atmosphere and wherein a force of the discharge is controlled electronically. However, the courts have stated patentability is based on the product, not the process by which it is made. Additionally, the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). Because Mirzabekov et al disclose the claimed structural components of the biochip, they disclose the biochip as claimed.

Regarding Claim 30, Mirzabekov et al disclose the biochip of Claim 3 wherein the base plate is non-permeable with respect to said capture solution i.e. glass (Column 6, lines 44-49 and Column 9, lines 7-10).

Response to Arguments

11. Applicant argues that biochip making method of Mirabekov et al utilizes a spotting similar to that of Audeh. Applicant states that for the reasons stated above regarding the Audeh reference, Mirabekov et al do not disclose the instant invention. The arguments have been considered but are not found persuasive as discussed above.

12. Claims 3, 4, 17, 18, 24, 25 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Chenchik et al (U.S. Patent No. 6,489,159 B1, filed 29 September 2000).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Art Unit: 1634

Regarding Claim 3, Chenchik et al disclose a biochip comprising a large number of spots of capture solutions containing a capture material therein arranged on a base plate wherein said plurality of capture solutions each of which is adapted to specifically react with a specimen (e.g. hybridize) and provide information about a structure within the specimen (Column 10, lines 17-24) and wherein said plurality of said spots are formed in which the concentration of the capture material varies from spot to spot and wherein each of said spots has a uniform detection sensitivity (Column 7, lines 49-64 and Claim 7). Chenchik et al do not teach the spots are supplied onto the base plate by means of an ink jet system. However, the courts have stated patentability is based on the product, not the process by which it is made. Therefore, the claimed biochip is unpatentable in view of the teaching of Chenchik et al.

Regarding Claim 4, Chenchik et al disclose the biochip wherein the spots are formed from the same capture solution i.e. total mRNA solution (Column 19, line 50-Column 20, line 29). While the spots comprise different oligonucleotides and therefore do not consist of the same capture solutions, they are formed from the same solution as claimed.

Regarding Claims 17 and 18, Chenchik et al disclose the biochip of Claims 3 and 4. While they do not teach the biochip spots are formed using an ink-jet system in which a sample solution is impacted onto said base plate after being discharged into the atmosphere and wherein a force of the discharge is controlled electronically, the courts have stated patentability is based on the product, not the process by which it is made. Additionally, the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). Because Chenchik et al disclose the claimed structural components of the biochip, they disclose the biochip as claimed.

Regarding Claims 24 and 25, Chenchik et al disclose the biochip of Claims 3 and 4. While they do not teach the biochip spots are formed using an ink-jet system in which a sample solution is impacted onto said base plate after being discharged into the atmosphere

Art Unit: 1634

and wherein the number of times of discharge at each spot is controlled electronically, the courts have stated patentability is based on the product, not the process by which it is made. Additionally, the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). Because Chenchik et al disclose the claimed structural components of the biochip, they disclose the biochip as claimed.

Regarding Claim 30, Chenchik et al disclose the biochip of Claim 3 wherein the base plate is non-permeable with respect to said capture solution e.g. glass (Column 6, lines 41-50).

Response to Arguments

13. Applicant argues that biochip making method of Chenchik et al utilizes a spotting similar to that of Audeh. Applicant states that for the reasons stated above regarding the Audeh reference, Chenchik et al do not disclose the instant invention. The arguments have been considered but are not found persuasive as discussed above.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1634

15. Claims 1, 2, 15, 16, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Audeh et al (U.S. Patent Application Publication No. 2002/0015958 A1, filed 4 May 2000) in view of Dean et al (U.S. Patent No. 5,843,662, filed 13 May 1996).

Regarding Claim 1, Audeh et al teach a biochip comprising a large number of spots of capture solutions containing a capture material therein arranged on a base plate wherein said plurality of capture solutions each of which is adapted to specifically react with a specimen (i.e. hybridize) and provide information about a structure within the specimen (§ 37) and wherein said plurality of said spots are formed in which the concentration of the capture material varies from spot to spot and wherein each of said spots has a uniform detection sensitivity (§ 30 and 31 and Claim 33). Audeh et al do not teach the spots have different spot sizes. However, Dean et al teach that a linear relationship exists between spot concentration and spot size i.e. increasing nucleic acid concentration produces spots of increasing size (Column 2, lines 43-67 and Fig. 1-5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made that the spots of Audeh et al which have different concentrations would also have different spot sizes. Alternatively, it would have been obvious to one of ordinary skill in the art to apply the different spot size-to-concentration relationship taught by Dean et al (Fig. 1-5) to the Audeh et al spots and to adjust the size of the spot to thereby provide the differing spot concentrations desired by Audeh et al (§ 30).

Additionally, Audeh et al do not teach the spots are supplied onto the base plate by means of an ink jet system. However, the courts have stated patentability is based on the product, not the process by which it is made. Therefore, the claimed biochip is unpatentable in view of the teaching of Audeh et al. and Dean et al.

Regarding Claim 2, Audeh et al disclose the biochip wherein the spots are formed from the same capture solution i.e. formed from the same colloidal suspension in water (§ 34). While the spots comprise different oligonucleotides and therefore do not consist of the same capture solutions, they are formed from the same solution as claimed.

Art Unit: 1634

Regarding Claims 15 and 16, Audeh et al disclose the biochip of Claims 1 and 2. While they do not teach the biochip spots are formed using an ink-jet system in which a sample solution is impacted onto said base plate after being discharged into the atmosphere and wherein a force of the discharge is controlled electronically, the courts have stated patentability is based on the product, not the process by which it is made. Additionally, the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). Because Audeh et al disclose the claimed structural components of the biochip, they disclose the biochip as claimed.

Regarding Claims 22 and 23, Audeh et al disclose the biochip of Claims 1 and 2. While they do not teach the biochip spots are formed using an ink-jet system in which a sample solution is impacted onto said base plate after being discharged into the atmosphere and wherein the number of times of discharge at each spot is controlled electronically, the courts have stated patentability is based on the product, not the process by which it is made. Additionally, the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). Because Audeh et al disclose the claimed structural components of the biochip, they disclose the biochip as claimed.

Response to Arguments

16. Applicant relies of the arguments presented above regarding the rejection under 102(e) over Audeh. The arguments have been considered but are not found persuasive as discussed above.

Art Unit: 1634

17. Claims 1, 2, 15, 16, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirzabekov et al (U.S. Patent No. 6,458,584 B1, filed 3 March 1999) in view of Dean et al (U.S. Patent No. 5,843,662, filed 13 May 1996).

Regarding Claim 1, Mirzabekov et al teach a biochip comprising a large number of spots of capture solutions containing a capture material therein arranged on a base plate wherein said plurality of capture solutions each of which is adapted to specifically react with a specimen (i.e. hybridize) and provide information about a structure within the specimen (Column 9, lines 20-30) and wherein said plurality of said spots are formed in which the concentration of the capture material varies from spot to spot and wherein each of said spots has a uniform detection sensitivity Column 18, lines 49-67) wherein the spots are supplied onto the base plate by means of an ink jet system i.e. peltier thermostated pin (Column 11, lines 45-48). Mirzabekov et al do not teach the spots have different spot sizes. However, Dean et al teach that a linear relationship exists between spot concentration and spot size i.e. increasing nucleic acid concentration produces spots of increasing size (Column 2, lines 43-67 and Fig. 1-5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made that the spots of Mirzabekov et al which have different concentrations would also have different spot sizes. Alternatively, it would have been obvious to one of ordinary skill in the art to apply the different spot size-to-concentration relationship taught by Dean et al (Fig. 1-5) to the Mirzabekov et al spots and to adjust the size of the spot to thereby provide the differing spot concentrations desired by Mirzabekov et al (Column 18, lines 49-62).

Regarding Claim 2, Mirzabekov et al teach the biochip wherein the spots are formed from the same capture solution i.e. formed from the same oligonucleotide synthesis solution (Column 11, lines 15-31 and Column 12, lines 8-10). While the spots comprise different

Art Unit: 1634

oligonucleotides and therefore do not consist of the same capture solutions, they are formed from the same solution as claimed.

Regarding Claims 15 and 16, Mirzabekov et al teach the biochip of Claims 1 and 2 wherein the biochip spots are supplied using an ink-jet system i.e. peltier thermostated pin (Column 11, lines 45-48). They do not teach the supplying wherein a sample solution is impacted onto said base plate after being discharged into the atmosphere and wherein a force of the discharge is controlled electronically. However, the courts have stated patentability is based on the product, not the process by which it is made. Additionally, the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). Because Mirzabekov et al disclose the claimed structural components of the biochip, they disclose the biochip as claimed.

Regarding Claims 22 and 23, Mirzabekov et al teach the biochip of Claims 1 and 2 wherein the biochip spots are supplied using an ink-jet system i.e. peltier thermostated pin (Column 11, lines 45-48). They do not teach the supplying wherein a sample solution is impacted onto said base plate after being discharged into the atmosphere and wherein a force of the discharge is controlled electronically. However, the courts have stated patentability is based on the product, not the process by which it is made. Additionally, the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). Because Mirzabekov et al disclose the claimed structural components of the biochip, they disclose the biochip as claimed.

Response to Arguments

18. Applicant relies of the arguments presented above regarding the rejection under 102(e) over Mirabekov et al. The arguments have been considered but are not found persuasive as discussed above.

Art Unit: 1634

19. Claims 1, 2, 15, 16, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenchik et al (U.S. Patent No. 6,489,159 B1, filed 29 September 2000) in view of Dean et al (U.S. Patent No. 5,843,662, filed 13 May 1996).

Regarding Claim 1, Chenchik et al teach a biochip comprising a large number of spots of capture solutions containing a capture material therein arranged on a base plate wherein said plurality of capture solutions each of which is adapted to specifically react with a specimen (e.g. hybridize) and provide information about a structure within the specimen (Column 10, lines 17-24) and wherein said plurality of said spots are formed in which the concentration of the capture material varies from spot to spot and wherein each of said spots has a uniform detection sensitivity (Column 7, lines 49-64 and Claim 7). Chenchik et al do not teach the spots have different spot sizes. However, Dean et al teach that a linear relationship exists between spot concentration and spot size i.e. increasing nucleic acid concentration produces spots of increasing size (Column 2, lines 43-67 and Fig. 1-5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made that the spots of Chenchik et al which have different concentrations would also have different spot sizes. Alternatively, it would have been obvious to one of ordinary skill in the art to apply the different spot size-to-concentration relationship taught by Dean et al (Fig. 1-5) to the Chenchik et al spots and to adjust the size of the spot to thereby provide the differing spot concentrations desired by Chenchik et al (Claim 7).

Additionally, Chenchik et al do not teach the spots are supplied onto the base plate by means of an ink jet system. However, the courts have stated patentability is based on the

Art Unit: 1634

product, not the process by which it is made. Therefore, the claimed biochip is unpatentable in view of the teaching of Chenchik et al. and Dean et al.

Regarding Claim 2, Chenchik et al teach the biochip wherein the spots are formed from the same capture solution i.e. total mRNA solution (Column 19, line 50-Column 20, line 29). While the spots comprise different oligonucleotides and therefore do not consist of the same capture solutions, they are formed from the same solution as claimed.

Regarding Claims 15 and 16, Chenchik et al teach the biochip of Claims 1 and 2. While they do not teach the biochip spots are formed using an ink-jet system in which a sample solution is impacted onto said base plate after being discharged into the atmosphere and wherein a force of the discharge is controlled electronically, the courts have stated patentability is based on the product, not the process by which it is made. Additionally, the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). Because Chenchik et al disclose the claimed structural components of the biochip, they disclose the biochip as claimed.

Regarding Claims 22 and 23, Chenchik et al teach the biochip of Claims 1 and 2. While they do not teach the biochip spots are formed using an ink-jet system in which a sample solution is impacted onto said base plate after being discharged into the atmosphere and wherein the number of times of discharge at each spot is controlled electronically, the courts have stated patentability is based on the product, not the process by which it is made. Additionally, the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). Because Chenchik et al disclose the claimed structural components of the biochip, they disclose the biochip as claimed.

Art Unit: 1634

Response to Arguments

20. Applicant relies on the arguments presented above regarding the rejection under 102(e) over Chenchik et al. The arguments have been considered but are not found persuasive as discussed above.

21. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1634


Conclusion

22. No claim is allowed.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
July 24, 2003